Serial No. 10/523,908 6102-000075/US/NP

Amendment and response to Office Action dated May 28, 2008 (Amendment B)

September 18, 2008

IN THE CLAIMS

The following listing of claims will replace all prior versions and listings of claims in

the present application.

1-27. (Canceled)

28. (Currently amended) A transdermal therapeutic system comprising a drug-containing

adhesive matrix, in which the drug is Rotigotine rotigotine ((-)-5,6,7,8-tetrahydro-6-

[propyl-[2-(2-thienyl)ethyl)amino]-1-naphthol) in form of a base or a prodrug of

Rotigotine rotigotine, wherein the adhesive matrix contains a hot-meltable adhesive,

the hot-meltable adhesive consisting of one adhesive or a mixture of different adhesives

or of a mixture of an adhesive and a softener and exhibiting at 160°C a dynamic

viscosity of not more than 100 Pa.s.

29. (Currently amended) The transdermal therapeutic system of claim 28 wherein

Rotigotine the base form of rotigotine or prodrug thereof is dispersed or partly or

completely dissolved in said hot-meltable adhesive.

30. (Currently amended) The transfermal therapeutic system of claim 28 wherein the drug-

containing adhesive matrix is produced by metering the Rotigotine the base form of

rotigotine or prodrug thereof into the solvent-free melt of the adhesive matrix at a

temperature of between 120°C and 160°C.

31. (Previously presented) The transdermal therapeutic system of claim 28 wherein the hot-

meltable adhesive consists of a mixture of an amine-resistant silicone adhesive and at

least one suitable softener.

32. (Previously presented) The transdermal therapeutic system of claim 31 wherein the

softener is an organic wax.

33. (Previously presented) The transdermal therapeutic system of claim 31 wherein the

softener is ceresine or ozokerite.

34. (Currently amended) The transdermal therapeutic system of claim 28 wherein the

proportion of Rotigotine the base form of rotigotine or prodrug thereof in the adhesive

Page 2 of 11

layer is 4 to 40 weight %.

- 35. (Currently amended) The transdermal therapeutic system of claim 28 wherein the proportion of **Rotigotine** the base form of rotigotine or prodrug thereof in the adhesive layer is 9 to 30 weight %.
- 36. (Currently amended) The transdermal therapeutic system of claim 28 wherein the proportion of **Rotigotine** the base form of rotigotine or prodrug thereof in the adhesive layer is 20 to 40 weight %.
- 37. (Currently amended) The transdermal therapeutic system of claim 28 wherein the drug is the base form of rotigotine Rotigotine or prodrug thereof is present as the active ingredient in form of a base.
- 38. (Withdrawn and currently amended) The transdermal therapeutic system of claim 28 wherein the drug-containing adhesive matrix additionally contains an internal-phase component selected from the group **consisting** of [:]
  - (a) hydrophilic [[or]] and amphiphilic polymers;
  - (b) hydrophilic [[or]] and amphiphilic copolymers;
  - (c) mixtures of (a) and/or (b) with pharmaceutically acceptable softeners;
  - (d) condensates from glycerin and fatty acids or polyols; and
  - (e) suitable mixtures of the components (a)–(d).
- 39. (Withdrawn and currently amended) The transdermal therapeutic system of claim 38 wherein the internal-phase component is selected from the group **consisting** of[[:]] polysaccharides, substituted polysaccharides, polyethylene oxides, polyvinyl acetates, polyvinyl pyrrolidones, copolymers from polyvinyl pyrrolidone and (poly)vinyl acetate, polyethylene glycol, polypropylene glycol, copolymers from ethylene and vinyl acetate, glycerin-fatty acid esters **as well as and** mixtures of polyvinyl alcohol with glycerin.
- 40. (Withdrawn and currently amended) The transdermal therapeutic system of claim 28 wherein the adhesive matrix comprises:
  - (a) 50–99 weight % of said hot-meltable adhesive;
  - (b) 4-40 weight % Rotigotine rotigotine in the base form;

Serial No. 10/523,908 6102-000075/US/NP Amendment and response to Office Action dated May 28, 2008 (Amendment B) September 18, 2008

- (c) 0-40 weight % of an internal-phase component; and
- (d) 0-10 weight % of other adjuvants.
- 41. (Currently amended) The transdermal therapeutic system of claim 28 wherein the hot-meltable adhesive is selected from among:
  - (a1) an EVA adhesive,
  - (a2) an SxS adhesive, or
  - (a3) a mixture of
    - (i) 70–99 weight % of an amine-resistant silicone adhesive and
    - (ii) 1–30 weight % of a suitable softener.
- 42. (Canceled)
- 43. (Currently amended) The transdermal therapeutic system of claim 28 wherein the system comprises a prodrug of **Rotigotine** rotigotine.
- 44. (Currently amended) The transdermal therapeutic system of claim 43 wherein the prodrug is an ester or carbamate of **Rotigotine** rotigotine.
- 45. (Withdrawn) A transdermal therapeutic system for administration of Rotigotine, comprising: a layer that comprises Rotigotine or a prodrug of Rotigotine, wherein the layer
  - (a) contains Rotigotine or prodrug thereof in a percentile proportion of at least 20 weight %,
  - (b) has a Rotigotine or prodrug thereof content of at least 2.0 mg/cm<sup>2</sup>, and
  - (c) optionally contains an organic wax and/or internal-phase component in an amount sufficient to retard the release of the active substance.
- 46. (Withdrawn) The transdermal therapeutic system of claim 45 wherein Rotigotine or prodrug thereof is transported through the skin at a steady-state flux rate of 100–500 μg per hour over a period of at least 5 days.
- 47. (Withdrawn) The transdermal therapeutic system of claim 45 wherein Rotigotine or prodrug thereof is transported through the human skin at a flux rate of 100–500 μg per hour over a period of at least 7 days.

- 48. (Withdrawn) The transdermal therapeutic system of claim 45 wherein the system induces in the patient an average plasma concentration of 0.4 to 2 ng/ml Rotigotine for a period of at least 5 days.
- 49. (Withdrawn) The transdermal therapeutic system of claim 45 wherein the system comprises Rotigotine.
- 50. (Withdrawn) The transdermal therapeutic system of claim 45 wherein the system comprises a prodrug of Rotigotine.
- 51. (Withdrawn) The transdermal therapeutic system of claim 50 wherein the prodrug is an ester or carbamate of Rotigotine.
- 52. (Withdrawn) A method for producing a transdermal therapeutic system that encompasses an adhesive matrix comprises Rotigotine or a prodrug of Rotigotine as the drug, the method comprising: prior to lamination components of the adhesive matrix are melted and homogenized, solvent-free, at temperatures of between 70°C and 200°C.
- 53. (Withdrawn) The method of claim 52 wherein components of the adhesive matrix are melted and homogenized in an extruder.
- 54. (Withdrawn) The method of claim 52 wherein the hot-melting process takes place at temperatures between 120°C and 160°C.
- 55. (Withdrawn) The method of claim 52 wherein Rotigotine or prodrug thereof is introduced, in the adhesive matrix melt, in its solid state.
- 56. (Withdrawn) The method of claim 52 wherein the adhesive matrix, produced by the hot-melting process, contains Rotigotine or prodrug thereof at a purity level of at least 98% as measured by HPLC at 220 nm and 272 nm.
- 57. (Withdrawn) The method of claim 52 wherein the system comprises Rotigotine.
- 58. (Withdrawn) The method of claim 52 wherein the system comprises a prodrug of Rotigotine.
- 59. (Withdrawn) The method of claim 58 wherein the prodrug is an ester or carbamate of Rotigotine.